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MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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February 25, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 2003N-0496
Food Health Claims and Dietary Guidance
68 Fed. Reg. 66040 (November 25, 2003)

The Grocery Manufacturers of America (GMA) submits these comments in response to the advance notice of proposed rulemaking (ANPR) that the Food and Drug Administration (FDA) published to solicit comment on issues related to health claims and dietary guidance for conventional food and dietary supplements, including alternatives for regulating qualified health claims in product labeling.

GMA is the world's largest association of food, beverage, and consumer product companies. Led by a board of 46 Chief Executive Officers, GMA applies legal, scientific, and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association also leads efforts to increase productivity, efficiency, and growth in the food, beverage, and consumer products industry. With United States sales of more than $500 billion, GMA members employ more than 2.5 million workers in all 50 states.

2003N-0496 C18

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EXECUTIVE SUMMARY

GMA submits these comments in response to the advance notice of proposed rulemaking (ANPR) that the Food and Drug Administration (FDA) published to address health claims and dietary guidance for conventional food and dietary supplements. The comments are consistent with, and adopt, comments that were submitted on May 14, 2003 and on January 20, 2004 by a Coalition composed of many of America's leading food industry associations and that are being resubmitted by the Coalition in response to this ANPR.

GMA strongly supports a premarket notification procedure of the type proposed by the Coalition and adopted by FDA in its interim guidance. As the Coalition has stressed, it is important that FDA publish a brief notice in the Federal Register both when a premarket notification is filed by the agency and when the agency issues its final decision on the matter. The final decision should also be posted on the FDA website.

It is essential that any evidence-based ranking system not be imposed in the rigid manner contemplated in the interim guidance and in Option 1 of the ANPR. Option 1 should be modified to clarify that the focus of any rating system is the relationship of the scientific evidence to the proposed health claim, and not to the underlying substance-disease relationship. The proposed qualifying language that corresponds to each of the identified ranks often will not be appropriate, and cannot be rigidly imposed. FDA should eliminate the letter grade designations it has proposed for each rank, and explicitly recognize the constitutional right of companies to fashion equivalent alternatives to the agency's model qualifying language.

GMA strongly opposes Option 2 because it would require excessive FDA and industry resources and an unjustified delay in the communication of valuable health information to consumers.

GMA supports elimination of the requirement that health claims include both the word "may" and the word "risk," and urges FDA to permit health claims that include only one of these two qualifiers.

GMA supports FDA's distinction between dietary guidance and health claims. GMA reminds FDA that it does not have authority to require premarket notification or approval for dietary guidance, and therefore under the First Amendment the agency may take enforcement action only if it can demonstrate that a dietary guidance statement is false or misleading. FDA may suggest dietary guidance, but companies may adopt or modify it as they choose as long as the outcome is truthful, accurate, and not misleading.

INTRODUCTION

Twice during the past year, a Coalition composed of many of America's leading food industry associations submitted consolidated comments to FDA regarding the regulation of qualified health claims. On May 14, 2003, the Coalition submitted comments to address FDA guidance on Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements.[1] This guidance set forth criteria FDA would consider when determining whether to exercise enforcement discretion in relation to a qualified health claim for conventional food and dietary supplement labeling. The Coalition comments proposed a specific FDA regulation to establish a premarket notification system for qualified health claims for food labeling.

On January 20, 2004, the Coalition submitted comments to respond to the publication of two FDA guidance documents, Interim Evidence-Based Ranking System for Scientific Data and

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[1] 67 Fed. Reg. 78002 (December 20, 2002).

Interim Procedures for Health Claims on the Labeling of Conventional Food and Human Dietary Supplements.[2] These guidance set forth the procedures and evidence-based ranking system for scientific data that FDA now uses on an interim basis to consider the exercise of its enforcement discretion with respect to qualified health claims for conventional food and dietary supplement labeling.

On November 25, 2003, FDA published its ANPR to solicit comments on proposed alternatives for regulating qualified health claims and other issues raised by FDA's Task Force on Consumer Health Information for Better Nutrition (the Task Force). GMA continues to support the positions articulated in the two prior comments of the Coalition, which are being resubmitted separately by the Coalition in response to this ANPR. We are also submitting these comments to address issues that FDA has raised in this ANPR.

I. HEALTH CLAIMS

A. Regulatory Alternatives for Qualified Health Claims

In contrast to unqualified health claims, provision for qualified health claims does not arise under the Federal Food, Drug, and Cosmetic Act (FD&C Act), but rather under the First Amendment to the Constitution of the United States.[3] Thus, qualified health claims are not subject to the premarket approval provisions of section 403(r)(1)(B) of the FD&C Act. Accordingly, FDA is free to establish any reasonable procedural requirements for qualified

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[2] 68 Fed. Reg. 41387 (July 11, 2003).

[3] *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), rehearing denied, 172 F.3d 72 (D.C. Cir. 1999) (en banc), 130 F. Supp. 2d 105 (D.D.C. 2001), 141 F. Supp. 2d 105 (D.D.C. 2001); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

health claims, as long as they satisfy due process and First Amendment requirements, as well as any applicable statutory provisions.

The ANPR requests comment on three options for regulating qualified health claims. Option 1 would essentially codify the interim guidance. GMA strongly supports a premarket notification procedure of the type proposed by the Coalition and adopted in the interim guidance. As the Coalition has pointed out, however, the evidence-based ranking system cannot be imposed in the rigid manner contemplated in the interim guidance and in Option 1.

The weight of the scientific evidence in support of a particular claim will not always fit neatly into the four-category scheme posited by the interim guidance and Option 1. Thus, the proposed qualifying language that corresponds to each of the categories will not be appropriate in some circumstances, and cannot be rigidly imposed. At most, such language could serve as a "safe harbor" that would permit a party adopting it to do so without further discussion, after submitting a premarket notification.

The First Amendment requires that FDA permit the use of any explanatory or qualifying terms that accurately convey the weight of the scientific evidence and that are not misleading. The sole focus must be on whether the claim conveys the scientific evidence on which the claim is based. If the claim is truthful and not misleading, FDA cannot prohibit its use.

The letter grades that FDA proposes to assign to qualified health claims, based upon the level of scientific evidence supporting them, are likely to confuse rather than inform consumers. Many consumers will interpret these grades as indicative of the health value or overall quality of the product, rather than the level of scientific evidence supporting the claim. The mere possibility of such confusion will discourage companies from petitioning FDA for use of a qualified health claim. Accordingly, FDA should eliminate the letter grade designations it has

proposed, and recognize the constitutional right of companies to fashion equivalent alternatives to the agency's model qualifying language. If it does not, FDA not only risks violating First Amendment rights, but also threatens to undermine the dissemination and value of the information that it seeks to promote. Option 1 should also be modified to clarify that the focus of any rating system is the relationship of the scientific evidence to the proposed health claim, and *not* to the underlying substance-disease relationship.[4]

GMA supports an open premarket notification procedure. FDA should publish in the Federal Register a short notice both when a premarket notification is filed by the agency and when a final determination is made by the agency on the requested qualified health claim. The final determination should be posted on the FDA website.

GMA strongly opposes Option 2 because it would require excessive FDA and industry resources and an unjustified delay in the communication of important health information to consumers. If modified as proposed both here and in the Coalition submissions, Option 1 would represent the best means of promoting communication of truthful, accurate, and nonmisleading qualified health claims.

B. Issues Raised in the Task Force Report

In its report, the Task Force recommended that FDA seek comment on a number of additional issues related to qualified health claims.

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[4] In its presentation of Option 2, FDA acknowledged that this view is consistent with section 403(r)(1)(B) of the FD&C Act. 68 Fed. Reg. at 66042.

1. Data and Research on a Substance/Disease Relationship, Including Incentives for SSA

It is rare that intellectual property rights exist for individual food categories, food components, or food ingredients. In contrast to research on prescription drugs, FDA lacks statutory authority to award market exclusivity for studies conducted on conventional food and dietary supplements. Thus, industry incentives to invest in research necessary to substantiate a health claim are extremely limited. Industry is unlikely to conduct such research except where companies that share an interest in the same food succeed in collaborating for such a purpose[5] or where the subject of the prospective health claim is marketed or manufactured by a company that possesses a share of the market that is large enough to offset the research costs.[6] Most research of this type will be sponsored by government agencies or academic institutions.

2. Revised Claim Language for Unqualified Health Claims

As noted in the ANPR, FDA regulations require unqualified health claims to state that the substance that is the subject of the claim "may" reduce the "risk" of the particular disease.[7] GMA agrees with FDA that the word "may" leads to uncertainty about the science behind the claim, since consumers are likely to interpret its use as a "reflection of the science supporting the claim rather than the certainty about the ability of a dietary practice to affect any one consumer."[8]

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[5] International Tree Nut Council Nutrition Research and Education Foundation, Nuts Health Claim Petition, Docket No. 02P-0505 (August 28, 2002).

[6] The Quaker Oats Co. and Rhodia, Inc., Oatrim (BETATRIM) Health Claim Petition, Docket No. 01Q-0313 (April 12, 2001).

[7] 69 Fed. Reg. at 66043 (citing 21 C.F.R. 101.14(d)(2)(ii)).

[8] *Id.*

As presently worded, significant scientific agreement (SSA) claims are qualified not only by use of the word "may" but also by use of the word "risk" rather than a direct reference to the harm involved. "May reduce heart disease" is roughly equivalent to "Reduces the risk of heart disease." Using both qualifiers ("May reduce the risk of heart disease") is both redundant and semantically incorrect. A reduction in risk does not mean, of course, that all potential harm has been eliminated. Thus, GMA supports eliminating one of the two qualifiers in all health claims. The person marketing the product should be permitted to use the "May reduce" version, or the "Reduces the risk" version, or the "May reduce the risk" version, based on its determination of which is more likely to be meaningful to consumers under the circumstances involved.

3. Interim Final Rules for Unqualified Health Claims

FDA reliance upon interim final rules (IFRs) for unqualified health claims has been essential to promoting enhanced communication regarding the health benefits of food. As FDA recognizes, "the value of commercial speech often depends upon its timeliness."[9] Accordingly, GMA supports FDA's continued use of IFRs to expedite the availability of health claims.

4. Use of Phrases Such as "FDA Authorized" in Qualified and Unqualified Health Claims

GMA supports continuation of FDA's current policy of prohibiting use of phrases such as "FDA authorized" or "FDA approved" in labeling, because such endorsements would be likely to confuse consumers. Consumers would undoubtedly interpret such phrases as applying to the entire product. Competitive pressure would force every product to use the "FDA approved" endorsement because of fear that consumers would always purchase a product with an FDA

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[9] 68 Fed. Reg. at 66043.

endorsement rather than one without it. As a result, the good name and reputation of FDA would be exploited for inappropriate commercial purposes.

5. Consumer Education

The focus of FDA should be on assuring that food labels provide accurate and useful nutrition information for the use of American consumers. This was the purpose of both the original nutrition labeling regulations promulgated by FDA in 1972 and the current regulations promulgated in 1993. No provision in the FD&C Act requires or authorizes FDA to initiate a consumer education program. Such an effort is not the most efficient or effective use of FDA's already overburdened resources.

It is appropriate for the private sector -- food companies and their trade associations, parents, and our educational system at all levels -- to undertake nutrition education, based on the Nutrition Facts box and the nutrient descriptors and health claims authorized by FDA. The primary function of FDA is to assure that the food label is truthful and useful.

The food label has limited space. It seldom has sufficient space for educational purposes. It is best used to provide factual information that underpins and is the foundation for nutrition education.

An important educational function that FDA could serve would be to reassure consumers that they can rely on the nutrition information on the food label with confidence. This is information that FDA regulates in detail. And when FDA determines that the nutrition information on a food label is false or misleading, the agency should bring appropriate enforcement action. This should be a high agency priority.

6. Evaluations of Outside Scientific Groups

GMA agrees with FDA that the findings, conclusions, and recommendations of outside scientific groups can make important contributions to understanding the relationship between diet and health or disease. But FDA should not attempt to classify outside scientific groups as "acceptable" or "unacceptable" or as "good" or "bad." The results of their deliberations should instead be evaluated on the basis of standard scientific criteria -- the training and experience of the individuals involved, the thoroughness of the evaluation that they have undertaken, the quality of the report they have produced, the scientific data and information on which they rely, and other similar factors. In short, each recommendation of an outside scientific group must be evaluated on the merits of the recommendation itself, not on the merits of the organization.

7. Competent and Reliable Scientific Evidence

As recognized by both *Pearson v. Shalala* and *Whitaker v. Thompson*, the First Amendment prohibits FDA from banning a health claim outright if "credible" scientific evidence exists to support the claim. In its prior comments, the Coalition has discussed the well-accepted elements that determine whether scientific evidence is or is not "credible." For example, scientific evidence is not credible if the protocol is not designed in a way that the study results in valid conclusions.

The Federal Trade Commission (FTC) has used the phrase "competent and reliable" scientific evidence to convey the identical concept. Competent and reliable evidence is credible, and credible scientific evidence is competent and reliable. This is a semantic distinction without a substantive difference.

GMA supports use of the "credible scientific evidence" terminology, rather than the FTC terminology, because "credible scientific evidence" is the standard that the courts have

determined is mandated by the First Amendment under the Nutrition Labeling and Education Act (NLEA) of 1990. Introducing the FTC terminology into the NLEA will result in confusion, rather than clarity, and undoubtedly provoke further unnecessary litigation. There is no valid policy purpose to be served by substituting the FTC "competent and reliable" terminology for the "credible" terminology articulated by the courts under the NLEA.

Rather than adopting the FTC terminology, FDA should focus instead on defining the "credible scientific evidence" standard that the courts have recognized that Constitution requires. The Coalition included such a definition in its May 14, 2003 comments. We continue to recommend that the standard of credible scientific evidence be satisfied by any scientific study that meets long-established principles of scientific investigation, *e.g.*, a written protocol with an adequate design and that describes the investigation in sufficient detail, informed consent of human study subjects, statistical analysis of results, and a written report reviewing the investigation and documenting appropriate conclusions. Such evidence may include *in vitro* data, results of animal experimentation, data on the mechanism of action involved in any nutrient-disease relationship, epidemiology, and any other form of scientific information. The evidence need not be published or peer-reviewed. The specific wording of the claim would determine the type and quantity of evidence required to support it.

C. Issues for Future Consideration

The decisions in *Pearson* and *Whitaker* make clear that FDA regulations relating to disqualifying nutrient levels[10] and minimum nutrient content requirements[11] violate First

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[10] 21 C.F.R. 101.14(a)(4).

[11] 21 C.F.R. 101.14(e)(6).

Amendment commercial speech protection. GMA urges FDA to expedite reconsideration of these issues.

II. DIETARY GUIDANCE

A. Regulatory Distinctions Between Dietary Guidance and Health Claims

GMA supports the distinction between health claims and dietary guidance that FDA has provided in the preambles to the final rules regulating health claims for conventional food[12] and dietary supplements[13] and in the ANPR. The agency has not applied this distinction consistently. For instance, FDA concluded that a statement about the health benefits associated with a diet that includes nuts was a health claim, even though the statement made no express or implied connection to any substance found in this broad class of food.[14] Accordingly, GMA urges FDA consistently to apply the health claim/dietary guidance distinction.

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[12] 58 Fed. Reg. 2478, 2487 (January 6, 1993).

[13] 59 Fed. Reg. 395, 418 (January 4, 1994).

[14] Letter from Christine L. Taylor, Director, FDA Office of Nutritional Products, Labeling and Dietary Supplements, CFSAN, to D. J. Soetart, President, International Tree Nut Council Nutrition Research and Education Foundation (July 14, 2003).

B. Issues Relating to Dietary Guidance

1. Definitions

GMA agrees with the current FDA distinction between a health claim and dietary guidance.

2. The Substance as the Subject of a Health Claim

Companies possess a First Amendment right to make any claim that is truthful, accurate, and nonmisleading. Unless FDA can demonstrate that a food-specific health claim (*e.g.*, "Yogurt reduces the risk of osteoporosis) is inaccurate or inherently misleading, it may not prohibit its use. FDA may require the use of a qualifying statement if empirical evidence demonstrates that it is needed to cure a potentially misleading statement.

Industry has special expertise in determining how best to communicate with consumers regarding the health benefits of its products. Companies have unique knowledge and experience in fashioning health-related messages that can best inform consumers. The limited resources of the agency are most appropriately allocated to ensuring that health claims for products already in the marketplace are truthful, accurate, and nonmisleading.

3. The Use of Food Category "Substitutions" or "Replacements" as a Form of Dietary Guidance

GMA appreciates FDA's interest in promoting messages that will positively affect the ability of consumers to choose healthful diets. Nonetheless, FDA has no authority to prohibit dietary guidance statements that recommend appropriate food or substance "substitutions" or "replacements" unless those statements are false or misleading. As FDA is aware, the agency lacks statutory authority to require premarket notification or approval of dietary guidance. Under the First Amendment, FDA may take enforcement action only if it can demonstrate that a dietary

guidance statement that contains a substitution or replacement recommendation is false or misleading.

4. Dietary Guidance on Food Labels

GMA has no objection to FDA developing a list of recommended dietary guidance subjects, but such recommendations cannot serve as model claims that must be rigidly incorporated. There are already a number of authoritative sources of dietary guidance from knowledgeable and reputable organizations and individuals. Companies are uniquely positioned to develop messages that will truthfully and accurately communicate with the public about their own products. Any effort by FDA rigidly to impose model dietary guidance statements would discourage companies from communicating this information, and thus would undermine FDA's objective in devising such statements. It is precisely because of FDA's complex and lengthy model health claims that very few companies use these claims. If companies are to use dietary guidance, they must be free to adopt or modify recommended statements, as long as the outcome is truthful, accurate, and not misleading.

III. FUTURE ANALYSIS OF BENEFITS AND COSTS

FDA requests comment on a number of questions relating to the costs and benefits of regulatory options for qualified health claims. GMA is unable to provide detailed answers to these questions because we lack sufficient information. The answers depend upon proprietary information that is typically closely guarded by individual companies. In general, however, the greater flexibility that FDA provides to the food industry, the more likely it is that companies will use their creativity to develop useful new products and claims. When FDA regulation becomes more rigid and inflexible (*e.g.*, the current model health claims), it imposes artificial

barriers to research, development, and competition in providing useful health information to consumers.

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